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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,378

11/27/2006

David Keith James

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EXAMINER

LAVERT, NICOLE F

ART UNIT

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3762

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,378	Applicant(s) JAMES ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 February 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/5/09, 6/13/08 & 1/30/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the appeal brief filed on 08/25/2010, PROSECUTION IS HEREBY
REOPENED. A new rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Niketa I. Patel/

Supervisory Patent Examiner, Art Unit 3762.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

New Grounds o

1. **Claims 1-39** are rejected under 35 U.S.C. 103 (a) as being unpatentable over Oriol et al. (US 2001/0014776) in view of Nagel (US 4,211,237), Beach (US 5,088,498) and Oriol et al. (US 5,596,993).

Oriol et al. discloses an apparatus (e.g., element 10) and a method for monitoring fetal behaviour {e.g., [0005] & (Figs 8 & 13)} comprising; an input for receiving ECG data; a waveform pre-processor (e.g., element 14) for identifying a succession of fetal ECG complex waveforms within the received data (e.g., [0019]-[0020]); a waveform processor (e.g., element 16) for determining differences in the shapes of a succession of fetal ECG complex waveforms over time (e.g., via disclosed 'fetal assessment process'), the waveform processor including at least one of a comparator for matching the ECG complex waveforms to a plurality of templates, and an event logger determining from the determined differences a number of fetal body movements (e.g., via disclosed 'fetal movement analyzer', element 36) during the period of time (e.g.,

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[0081]-[0082], [0094] & [0102]-[0103]). Note that the Examiner is interpreting the discloses trend variables, in which include data received over a period of time, and are further represented as trend plots on a ECG monitor as being the technique-means used to match fetal ECG complex waveforms to a plurality of templates, as is instantly claimed, used in order to facilitate the assessment of fetal states by reviewing data and evaluating said data by measuring and/or comparing the data against specific, fetal patterns [e.g., 0131].

Oriol et al. discloses the claimed invention having an apparatus and a method for monitoring fetal behaviour comprising an input for receiving ECG data except wherein said ECG data is from a set of electrodes adapted to be attached to a maternal abdomen positioned at different locations and wherein a waveform pre-processor for detecting phase changes between successive fetal ECG complex waveforms in addition to the pre-processor determining a difference in fetal complex waveforms by detecting a change in the positive and/ or negative energy of the fetal ECG complex waveform relative to a reference wherein an alarm is associated with said monitored fetal behavior . Nagel teaches that it is known to use a method for identifying occurring signals that are part of a signal mixture, i.e. identifying fetal QRS complexes from a maternal-fetal signal mixture, in which said fetal signals are subtracted from maternal signals, wherein said signals are received from various electrodes (e.g., elements 301-303) fastened to the body of a female patient [e.g., (col 9, ln 62-68), (col 10, ln 1-4) & (Fig 2)]. Beach et al. teaches that it is known to use a phase detector, which determines the approximate phases for ultrasounds reflected at each of several different depths (e.g., col 4, lines 5-

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11). Oriol et al. teaches that it is known to use a time plot of the baseline heart rate signal, in which the plot shows decelerations associated with loss of variability [e.g., (col 9, lines 60-67) & (Figure 5A)]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus and method as taught by Oriol et al. with the various electrodes disposed on a female patient used to receive both fetal and maternal ECG signals as taught by Nagel et al., with the phase detector as taught by Beach et al. and with the use of a time plot-representation of the baseline heart rate signal, in which the plot shows decelerations associated with loss of variability and a monitoring system as taught by Oriol et al. since such a modification would provide the apparatus and a method for monitoring fetal behaviour for providing the predictable results pertaining to receiving and/or recording fetomaternal EKG signals via multiple electrodes displaced on a mother's body in order to receive signal to determine the ECG of a fetus [e.g., Nagel, (col 9, ln 62-68), (col 10, ln 1-4) & (Fig 2)], a providing a precise indication for the distance traveled by the reflective tissue of a fetus (e.g., Beach, col 4, lines 10-11) and showing the appearance and temporal relations to contractions of a heart rate signal so that a physician can evaluate a newborn's heart rate, and in order to provide output data, such as warnings and recommendation, to the clinician [e.g., Oriol, (col 9, ln 40-42 & 63-67) & (col 19, lines 39-40 & 54-56)].

Response to Arguments

Applicant's arguments filed 25 August 2010 have been fully considered but they are not persuasive. The applicant argues the following points and in reference to each

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point the examiner provides a reason as to why she does not agree with the corresponding argument:

- The applicant argues that the primary reference, Oriol, does not determine the differences in the shapes of a succession of fetal ECG waveforms over time since the disclosed processor/feature extraction system does not accomplish the claimed limitation.

The examiner disagrees and further points out that Oriol et al. discloses a fetal data processing system and method by way of analyzing a fetal heart rate time series spanning a time period via analyzing the output of an expert subsystem (e.g., element 6) in which an user is presented with data via said subsystem pertaining to the evaluation of specific patterns of fetal ECG data such as variable and/or lateral decelerations in addition to presenting trend plots defined by output classifiers, wherein said decelerations provide variable complex waveform shapes that the subsystem can distinguish changes from therefore providing a means of determining differences in shapes of a succession of fetal ECG waveforms over time as is instantly claimed (e.g., [0130]-[0131]).

- The applicant argues that the examiner's interpretation of the trend variables as being the technique or means that is being used to match the claimed waveforms to the template is erroneous since the paragraph cited by the examiner implies that the clinician versus the processor is analyzing the ECG waveforms in which is opposite from the claimed invention.

The examiner disagrees and further points out that Oriol discloses that the expert subsystem (e.g., element 16) is what provides the configuration and output of data used in order to an assessment of fetal status in which the clinician then accepts the data received from said subsystem after reviewing the data displayed. Therefore, the interpretation of the disclosed trend variables, in which include data received over a period of time, and are further represented as trend plots on a ECG monitor and the technique-means used to match fetal ECG complex waveforms to a plurality of templates, as is instantly claimed, is used in order to facilitate the assessment of fetal states by reviewing data and evaluating said data by measuring and/or comparing the data against specific, fetal patterns [e.g., 0131].

- The applicant argues that Oriol does not teach using a template but rather mentions a "specific parameter," but this does not refer to a template that has been stored in a memory.

The examiner disagrees and further points out that the disclosed expert subsystem outputs and displays data so that an user can evaluate said data based on specific patterns, i.e. templates of fetal decelerations to as to automatically present trend plots based on a stored collection Of data (e.g., [0131]-[0133]).

- The applicant argues that Oriol et al. does not discloses a phase detector, an integrator or a comparator for matching the waveforms to a plurality of stored templates and/or for detecting change in the phase and/or amount of energy in the fetal ECG complex.

The Examiner disagrees with this assertion in view of the new rejection set forth above based on the submitted amendments.

- The applicant argues that neither Oriol nor Nagel teach a waveform processor that includes a discriminator for distinguishing between the maternal and fetal ECG complex waveforms.

The Examiner disagrees and further points out that Nagel discloses a means of distinguishing between and/or identifying maternal and fetal QRS complexes [e.g., (col 1, ln, 6-13) & (col 9, ln 62-68)-(col 10, ln 1-4)].

- The applicant argues that neither of the cited references teach that a template stored within the waveform processors corresponds to a specific fetal spatial presentation and/or positions.

The examiner disagrees and further points out that the disclosed expert subsystem outputs and displays data so that an user can evaluate said data based on specific patterns, i.e. templates of fetal decelerations to as to automatically present trend plots based on a stored collection Of data (e.g., [0131]-[0133]) wherein the expert subsystem (e.g., element 6) presents an user with data via said subsystem pertaining to the evaluation of specific patterns of fetal ECG data such as variable and/or lateral decelerations, i.e. data representative of fetal spatial presentation and/or position, in addition to presenting trend plots defined by output classifiers, wherein said decelerations provide variable complex waveform shapes that the subsystem can distinguishes changes from therefore providing a means of determining differences in

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shapes of a succession of fetal ECG waveforms over time as is instantly claimed (e.g., [0130]-[0131]).

- The applicant argues neither Oriol nor Nagel teach that the event logger records occasions on which the determined template changes.

The examiner disagrees and further points out that Oriol teaches that the stored templates can be automatically invoked and/or adjusted if a specific fetal movement signal becomes available, in which the user could define and/or store their own template [e.g., 0133].

- The applicant argues that it would not have been obvious to combine Oriol and Nagel with Beach since the technologies used a very different.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, the examiner points out that the argument is moot since it has been found that it would have been obvious to combine the two reference since said combination would provide the method and an apparatus for monitoring fetal behavior with a processing means for detecting phase changes between successive fetal ECG complex waveforms for

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providing the predictable results pertaining to a providing a precise indication for the distance traveled by the reflective tissue of a fetus (e.g., Beach, col 4, lines 10-11).

- The applicant argues that no combination of the cited prior art provides the claimed changes in the positive and/or negative energy of the fetal waveform that can be used to determine when the shape of the waveform has changed thereby indicating different fetal spatial presentation or position.

The examiner disagrees and further points out that Oriol discloses a time plot of the a baseline heart rate signal wherein said plot shows deviations and/or decelerations as compared to said baseline thus displaying differences in the fetal complex waveforms by change in the positive and or negative energy of the fetal ECG complex waveform relative to a reference so that a physician can evaluate a newborn's heart rate, and in order to provide output data, such as warnings and recommendation, to the clinician, in respect to information regarding the fetal presentation and/or presentation via the analysis of said decelerations [e.g., Oriol, (col 9, ln 40-42 & 63-67) & (col 19, lines 39-40 & 54-56)].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571-272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762